**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

| | | |
|---|---|---|
| Applicant: | David B. Krig et al. | Examiner: George Robert Evanisko |
| Serial No.: | 09/316,515 | Group Art Unit: 3762 |
| Filed: | May 21, 1999 | Docket No.: 279.112US1 |
| Title: | METHOD AND APPARATUS FOR TREATING IRREGULAR VENTRICULAR CONTRACTIONS SUCH AS DURING ATRIAL ARRHYTHMIA | |



## AFFIDAVIT OF JESSE W. HARTLEY UNDER 37 CFR § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This affidavit is submitted under 37 CFR § 1.132 before the final rejection of U.S. Patent Application Serial Number 09/316,515 (the "Application," filed on May 21, 1999) to establish the inapplicability of using the "Pacemaker System Guide for PULSAR MAX II; Mulitprogrammable Pacemakers" reference ("the Printed Document") in the rejections under 35 U.S.C. § 102(a) and under 35 U.S.C. § 102(a)/103(a) in the Office Action mailed on March 1, 2004.

I, Jesse W. Hartley, declare and say as follows:

1. I am a joint inventor with David B. Krig, Wyatt Stahl, and Jeffrey E. Stahmann of the subject matter claimed in the above-identified Application, as set forth in the May 21, 1999 Combined Declaration and Power of Attorney submitted with the Application.

2. The subject matter claimed in the patent application was invented while the above-named joint inventors were employed by the Cardiac Pacemakers, Inc. subsidiary of Guidant Corporation.

3. Upon information and belief, the above-identified Printed Document that was printed by our employer, Cardiac Pacemakers, Inc., on or about April 18, 1999, was not publicly released outside of Cardiac Pacemakers, Inc. before the May 21, 1999 filing date of the present Application, as discussed further below.

4. The information upon which this belief is based was obtained in part from Lori Kagel, Manager of Technical Communications at Cardiac Pacemakers, Inc., and Kristine Teich, Manager of Regulatory Affairs at Cardiac Pacemakers, Inc. Ms. Kagel and Ms. Teich examined our historical company data pertaining the Printed Document. They determined that it is our

standard company practice to not release product documentation such as the Printed Document outside of Cardiac Pacemakers, Inc. until such product documentation is shipped with its accompanying product, except for any submissions of such product documentation as "labeling" to regulatory approval agencies, which hold such submissions confidential. According to the historical company records examined by Ms. Kagel, the first such regulatory submission that would possibly include the Printed Document was confidentially made on August 31, 1999 to the British Standards Institute ("BSI"), which grants the "CE Mark," which is a prerequisite requirement for European implant of the product accompanied by the Printed Document. According to the historical company records examined by Ms. Kagel, approval for the "CE Mark" was granted on October 7, 1999. According to an October 13, 1999 press release from the Cardiac Pacemakers, Inc. subsidiary of Guidant Corporation, the first worldwide implants of the PULSAR MAX II device took place on October 12, 1999 in each of The Netherlands, Austria, England, and France. Therefore, based on our standard company practices and these dates, it is my belief that the Printed Document was not available outside of Cardiac Pacemakers, Inc. before the May 21, 1999 filing date of the present Application.

5. I have reviewed the Office Action mailed on March 1, 2004 for the examination of the Application, and I have also reviewed the portions of the Printed Document that were cited in that Office Action.

6. That information in the above-named Printed Document by our employer that relates to "ventricular rate regularization" was derived from the above-named joint inventors of the Application.

7. To the best of my knowledge, the ventricular rate regularization feature described in the above Printed Document was not used in any Cardiac Pacemakers, Inc. products before the Pulsar MAX II product, which was first used on October 12, 1999 in the European countries listed above.

8. I further declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the

United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

23-June-04
Dated

Jesse W. Hartley